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No. 01-1492

Supreme Court, U.S.
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IN THE
Supreme Court of the United States

MYLAN PHARMACEUTICALS INC.,

Petitioner,

v.

TOMMY G. THOMPSON, SECRETARY OF HEALTH AND HUMAN SERVICES, BERNARD A. SCHWETZ, D.V.M., PH.D., ACTING PRINCIPAL DEPUTY COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION, and U.S. FOOD AND DRUG ADMINISTRATION,
and
BRISTOL-MYERS SQUIBB CO.

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF FOR PETITIONER

E. ANTHONY FIGG
Counsel of Record
Robert Hector Cameron II
ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K Street, N.W.
Suite 800
Washington, D.C. 20005
(202) 783-6040
Counsel for Petitioner
Mylan Pharmaceuticals Inc.

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INTRODUCTION

The Federal Defendants do not dispute that Mylan's action seeking a declaratory judgment that Bristol's '365 patent was improperly listed in the FDA's Orange Book arose under the patent laws. They do not dispute that the Federal Circuit's dismissal of the action on jurisdictional grounds was incorrect and conflicted with this Court's precedent in *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, *reh'g denied,* 497 U.S. 1047 (1990).

Respondents, Bristol and the Federal Defendants, argue that this Court's review of the Federal Circuit's decision is unwarranted, because the Southern District of New York in *In re Buspirone Patent & Antitrust Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) has found on summary judgment that Bristol's patent is not infringed by Mylan or that the patent is invalid. They point out that generic versions of buspirone have been introduced in the marketplace. Bristol Br. 15; Fed. Def. Br. 14.

However, Respondents do not - and cannot - argue that this case is moot for purposes of further appellate review. Bristol acknowledges that it has appealed the judgment of the Southern District of New York. Bristol Br. 6 n.2. Bristol has not waived its right to re-list the '365 patent, nor has it waived recovery of damages on the $25 million preliminary injunction bond submitted by Mylan in the event that the New York court's summary judgment is overturned.

The Federal Defendants appear to concede that the issue presented by this case is worthy of review by this Court (Fed. Def. Br. 13-14), but that a better case may come along. This argument is logically flawed. Both the patent-listing provisions of the FDCA (21 U.S.C. §§ 355(b)(1) and (c)(2))

and the patent infringement statute (35 U.S.C. § 271(e)(2)) contain the same requirements with respect to the involved patent -- that it claims the drug or a method of using such drug. Thus, when a patent is listed improperly in the Orange Book, it is also likely that the ANDA applicant's product will not infringe under § 271(e)(2). Leaving aside the fact that the Federal Circuit's decision, if left undisturbed, will be a powerful disincentive for future ANDA applicants to challenge improper patent listings, by the time a future case reaches this Court, its procedural posture will likely be similar to that of this case.

The Federal Defendants argue that because of the summary judgment entered in the infringement case in New York, generic buspirone products would have been kept off the market only for fifteen months as a result of Bristol's improper listing of the '365 patent.[1] Fed. Def. Br. 15. Of course, during this fifteen-month period, the public would have been forced to pay monopoly prices amounting to increased costs of hundreds of millions of dollars for a drug whose legitimate patent life had expired. Reversal of the Federal Circuit's decision will make it possible for generic drug companies to challenge improper listings before getting bogged down in complicated and lengthy patent infringement lawsuits - - lawsuits that automatically delay FDA approval of their products.

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[1] Because of the injunction entered by the District Court in this case, Mylan's generic buspirone was actually kept off the market for about five months.

I. Mylan's Declaratory Judgment Action Arises Under the Patent Laws

A. With respect to the first and second questions presented in the Petition, the Federal Defendants' response is as important for what it does not say as it is for what it says. The Federal Defendants explained that their position before the Federal Circuit was that Mylan's declaratory judgment action was cognizable under the patent laws and that the "district court had properly exercised subject-matter jurisdiction over the case." *See* Fed. Def. Br. 11. The Federal Defendants have done nothing to alter their position. Rather, they represent that, "[d]espite the court of appeals' contrary holding, the jurisdictional question does not warrant this Court's review, *at least in the context of the present suit*." Fed. Def. Br. 13-14 (emphasis added). Thus, the Federal Defendants, by implication, have acknowledged that the Federal Circuit reached an erroneous conclusion on a significant issue of jurisdiction under the Declaratory Judgment Act.

B. Bristol misapprehends the nature of Mylan's defense to the threatened action for infringement under 35 U.S.C. § 271(e)(2). Bristol argues that the Hatch-Waxman Amendments do not expressly create the defense to patent infringement upon which Mylan relies in seeking declaratory judgment, and that this "demonstrates conclusively that there is no such defense." Bristol Br. 11. This argument is conclusory and simply wrong -- it overlooks that the defense of improper patent listing in the Orange Book arises under the patent laws because it is in effect a defense that Bristol cannot assert a cause of action under 35 U.S.C. § 271(e)(2). Unless there is a properly listed patent, the "artificial act" of

infringement (the filing of a Paragraph IV certification), which gives rise to an action under § 271(e)(2)(A), does not exist. *See Eli Lilly & Co.*, 496 U.S. at 678. Lack of a cause of action is a defense available to a party to a patent infringement suit, and it was unnecessary for Congress to have so provided explicitly.

Furthermore, Bristol ignores the relationship between the language used in the patent-listing requirements of § 355(c)(2) of the FDCA and that in the requirements for a cause of action under § 271(e)(2). These two provisions closely parallel one another. A basic canon of statutory construction is that Congress' use of identical terms within an Act reflects that they have the same meaning. *See Varity Corp. v. Howe*, 516 U.S. 489, 523 (1996). Thus, a patent may properly be listed under 21 U.S.C. § 355(c)(2) only if it claims the approved drug or a method of using it. Similarly, the patentee may properly assert a cause of action under § 271(e)(2)(A) only if the patent claims the drug or a method of using it. A defense of failure to state a claim derives from the language used in the interrelated statutory provisions.

II. There Is a Conflict Presented By the Court of Appeals' Decision Below and this Court's Statutory Construction of 35 U.S.C. § 271(e)(2)

Bristol seeks to minimize the conflict between the decision below and this Court's holding in *Eli Lilly & Co.* by arguing that the latter case did not involve the issue of whether there existed an improper patent-listing defense. Bristol Br. 11 n.5. Mylan does not contend that this Court's holding in *Eli Lilly & Co.* created an improper patent-listing defense. But in *Eli Lilly & Co.*, the Court construed 35 U.S.C. § 271(e)(2) and determined that it gave rise to a cause

of action for patent infringement when an ANDA was submitted ". . . containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug . . . *violates the relevant patent*." *Eli Lilly & Co.*, 496 U.S. at 678 (emphasis added). The Court's construction of the statute leads to the conclusion that, unless a patent is properly listed in the Orange Book, no cause of action for infringement under § 271(e)(2) exists. A patent that has not been properly listed in the Orange Book (which, as all parties concede, triggers the need to file the Paragraph IV certification) cannot be "relevant." The Federal Circuit failed to recognize this point when it held that no cognizable claim for declaratory judgment existed under the patent laws. Hence, the Federal Circuit's construction of this statute contravenes this Court's interpretation of the Hatch-Waxman Amendments in *Eli Lilly & Co.*

III. The Court of Appeals Did Not Properly Resolve Whether Mylan's Declaratory Judgment Action Was Barred Under 21 U.S.C. § 337(a)

Respondents differ in their positions concerning the third question presented, namely whether 21 U.S.C. § 337(a) precludes an ANDA applicant from bringing an action for declaratory judgment that a patent has been improperly listed in the FDA's Orange Book. Bristol argues that under § 337(a), Mylan's declaratory judgment action is not permitted. Bristol Br. 7-9. In contrast, the Federal Defendants have not disputed Mylan's position that its declaratory judgment action arises under the patent laws and therefore is not barred by § 337(a). *See* Fed. Def. Br. 12 n.5, 15. In their response, the Federal Defendants *only* disputed Mylan's argument concerning the application of § 337(a) to the patent-listing provisions of the Hatch-Waxman

Amendments presuming, *arguendo*, that the instant suit arose under the FDCA and not the patent laws. *See* Fed. Def. Br. 15. By singling out Mylan's statutory construction of § 337(a) but not the third question presented in the Petition, the Federal Defendants have acknowledged a conflict between their position on how § 337(a) is applied to the instant case and the position taken by the Federal Circuit.

Bristol advances two arguments in support of its contention that the Federal Circuit correctly determined that § 337(a) barred Mylan from bringing its declaratory judgment action based on an improper patent listing: (1) there exists no express provision in the FDCA supporting a private right of action involving an improper patent listing; and (2) Mylan's purported statutory construction of § 337(a) is incorrect because the Hatch-Waxman Amendments did not disturb well-settled law that § 337(a) precludes private rights of action to enforce violations of the FDCA. These contentions are without merit for the reasons discussed below.[2]

A. Section 337(a) expressly refers to enforcement or restraint of violations of that statute. Yet, the Hatch-

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[2] Bristol represents that there "could not be a clearer example of a private litigant attempting to enforce the FFDCA" in this case. Bristol Br. 8. This statement is wrong, as the decision below demonstrates. The Federal Circuit first examined whether there was a jurisdictional basis for Mylan's declaratory judgment claim under the patent laws and the Hatch-Waxman Amendments *before* reaching the issue of the application of § 337(a) to the case. *See* App. 14a-18a. Only when the Federal Circuit concluded that Mylan's declaratory judgment claim did not arise under the patent laws or under the Hatch-Waxman Amendments was it "...forced to conclude that Mylan's action here against Bristol is in essence an attempt to assert a private right of action for 'delisting' under the FFDCA." App. 18a.

Waxman Amendments were made both to the FDCA and to Title 35 of the United States Code relating to patents. The decision below concludes that: "[A] number of the Hatch-Waxman Amendments constitute part of the patent laws, and are essential to defining whether a defense to infringement is available under 35 U.S.C. § 271(e)(2)(A)." App. 16a n.2. The case law cited by Respondents, particularly *Mylan Labs., Inc. v. Matkari,* 7 F.3d 1130 (4th Cir. 1993), *cert. denied sub nom. American Home Prods. v. Mylan Labs.*, 510 U.S. 1197 (1994) and *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.,* 902 F.2d 222 (3d Cir. 1990), also supports that a private right of action may be brought under another Federal statute (in those cases, the Lanham Act) relying on standards set forth in the FDCA, so long as such claims do not require original interpretation of the FDCA or its accompanying regulations promulgated by the FDA. *See Sandoz*, 902 F.2d at 231; *Matkari,* 7 F.3d at 1138.

In this case, Mylan's declaratory judgment action is predicated on Bristol's listing a patent in the Orange Book which does not claim the listed drug or claim a use for such listed drug. *See* 21 U.S.C. § 355(c)(2). The Federal Defendants correctly point out in their response that the term "claims" in the afore-mentioned provision of the FDCA has been used in patent legislation since as early as 1836 to define the invention that an applicant believes to be patentable. *See* Fed. Def. Br. 3 n.1. According to the Federal Circuit, "[i]n order for a patent to 'claim' a product, the patentee must have satisfied numerous tests of patentability..." *Hoechst-Roussel Pharms., Inc. v. Lehman,* 109 F.3d 756, 758 (Fed. Cir. 1997). Hence, Mylan's declaratory judgment action does not require original interpretation of the FDCA or the FDA's accompanying regulations and therefore is not barred by § 337(a).

B. Neither Bristol nor the Federal Defendants offer any explanation of the term "such proceedings" in § 337(a). They ignore that term and instead interpret the statute as if it reads "all proceedings."[3] The only reasonable interpretation of the statute is that "such proceedings" means the proceedings that Congress enumerated in the preceding sections of Subchapter III. Those sections make no provision for the government to enforce the patent-listing provisions of the Hatch-Waxman Amendments. It is illogical for the Federal Defendants to argue on one hand that the FDA has no power (or expertise) to enforce the patent-listing provisions (App. 163a) and on the other hand that § 337(a) reserved to the FDA the exclusive right to enforce those provisions.

C. Consistent with Mylan's interpretation of the statute, in *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001), the Court held that the "FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for non-compliance with the *medical device provisions* . . ." *Buckman,* 531 U.S. at 349 n.4 (emphasis added). In this manner, the Court was careful to limit its holding to the issue before it and made no general pronouncement that all private actions under the FDCA are barred. In fact, none of the authorities cited by Respondents (Bristol Br. 8-9; Fed. Def. Br. 16) involve actions unrelated to issues of safety and health. If the Federal Circuit's broad

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[3] Respondents cite a federal district court decision, *Nat'l Women's Health Network, Inc. v. A. H. Robins Co., Inc.*, 545 F. Supp. 1177 (D. Mass. 1982), which rejects an argument that "such proceedings" in the statute limits the forms of equitable proceedings reserved to exclusive government enforcement. This decision is not instructive on the subject of the application of § 337(a) to enforcement proceedings not covered in the preceding sections of Subchapter III.

interpretation of the statute were correct, there would have been no need for this Court to have limited its holding to the enforcement of "medical device provisions" - - provisions that are provided in Subchapter III. The Court undoubtedly was aware of the line of cases cited by Respondents and upon which the Federal Circuit relied in its opinion. For this reason, contrary to Bristol's reasoning that *Buckman* is consistent and generally supportive of the decision below (Bristol Br. 9), the Court of Appeals extends the line of precedent cited by Respondents beyond the scope of this Court's statutory construction of § 337(a) and thus contravenes the authority of this Court.

IV. 21 U.S.C. § 355(j)(5)(B)(iii) Does Not Bar Mylan From Bringing Its Declaratory Judgment Action

Bristol also claims that 21 U.S.C. § 355(j)(5)(B)(iii) bars Mylan from bringing its declaratory judgment action. Bristol Br. 12. This is incorrect.

At the time Bristol's '365 patent issued and was listed, Mylan's ANDA had been tentatively approved by the FDA. Final approval and commercial marketing were expected to occur the next day. Therefore, Mylan was imminently prepared to commence allegedly infringing activity – the filing of a Paragraph IV certification. Bristol admitted at oral argument in the Federal Circuit that its listing of the '365 patent, together with its public statements and conduct, placed Mylan in reasonable apprehension of a Hatch-Waxman lawsuit. App., *infra*, 181a. Therefore, Mylan brought this declaratory judgment action seeking an adjudication of its rights *before* filing a Paragraph IV certification and before the forty-five day period referred to in § 355(j)(5)(B)(iii) was implicated at all.

In *DuPont Merck Pharms. Co. v. Bristol-Myers Squibb Co.*, 62 F.3d 1397 (Fed. Cir. 1995), the Federal Circuit addressed precisely this same situation and held that a declaratory judgment action was not barred. In that case, DuPont Merck filed a declaratory judgment action *before* filing an ANDA with a Paragraph IV certification. Bristol argued in that case, as here, that DuPont Merck's action was barred by § 355(j)(5)(B)(iii). The Federal Circuit rejected that argument and reached the merits of the action. *Id.* at 1401. Similarly here, Mylan's action is not barred by the statute and the requisite justiciable controversy for declaratory judgment exists.

CONCLUSION

For the foregoing reasons, Mylan respectfully requests that its *certiorari* be granted.

Respectfully submitted,

E. Anthony Figg
Counsel of Record
Robert Hector Cameron II
ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K Street, N.W.; Suite 800
Washington, D.C. 20005
(202) 783-6040
Counsel for Petitioner
Mylan Pharmaceuticals Inc.